Taste and smell disturbances in patients with gastrointestinal stromal tumors using tyrosine-kinase inhibitors.

Gepubliceerd: 25-06-2019 Laatst bijgewerkt: 13-12-2022

It is hypothesized that taste and smell disturbances are common among GIST patients using TKIs.

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON21230

Bron
NTR

Verkorte titel
TBA

Aandoening

Gastro-intestinal stromal tumors

Ondersteuning

Primaire sponsor: University Medical Center Groningen
Overige ondersteuning: n.a.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

What is the prevalence of taste and smell disturbances in GIST patients using TKIs?

Toelichting onderzoek

Achtergrond van het onderzoek

This study will be conducted at the University Medical Center Groningen (UMCG). Patients who are currently treated with a TKI for a GIST and understand spoken and written Dutch will be included. Fifty eligible patients will be asked to participate. At this moment, around fifty patients are currently treated with TKIs for a GIST at the UMCG. Based on a recent study on taste alterations in oncological patients receiving systemic therapy, it is expected that this number is sufficient to provide meaningful data. The potential participants are derived from the patient database of the Dutch GIST registry that is open for all patients diagnosed with a GIST. Potential participants will be screened in the objection registry of the UMCG. Patients who are registered will not be invited to participate in this study. Patients who are not registered will be send a letter that explains the study design and mentions that they will receive a telephone call. The potential participants will be asked to answer questions regarding taste disturbances by phone. This call will last approximately fifteen minutes. At any moment, they can decide to withdraw from the study. When patients pick up the phone, they will be asked explicitly for consent to participate. If consents is given, participants will answer the questionnaire.
The questionnaire that is used in this study (see supplement) is based on two previously used questionnaires which, respectively, were designed 1) to study metallic taste in patients who undergo systemic cancer therapy and 2) to study the impact of taste and smell alterations on the liking of specific nutritional supplements during systemic anti-cancer therapy. Information about the medical history of the patients and their current use of TKIs will be collected from the patients electronic file after the phone call and will not be part of the questionnaire.
The primary outcome of this questionnaire will be the proportion of patients reporting taste and smell alterations. The secondary outcome will be data on the type of taste disturbances and in particular alterations of bitter, sweet, salt, sour, metallic and a continuous taste. Furthermore, insight in the relation with the impact on daily life and QoL of the participants will be provided.

Doel van het onderzoek

It is hypothesized that taste and smell disturbances are common among GIST patients using TKIs.

Onderzoeksopzet

Start July 15, finish December 1 - 2019

Onderzoeksproduct en/of interventie

Patients will be interviewed by phone about taste alterations. Information about the background of the patients, including gender, age and type and treatment of the GIST, will be collected from the patients electronic file.

Contactpersonen

Publiek

University Medical Center Groningen
Jacco de Haan

050-361281

Wetenschappelijk

University Medical Center Groningen
Jacco de Haan

050-361281

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Pathologically confirmed diagnosis of a GIST
- Currently treated with imatinib, sunitinib or regorafenib
- Able to understand spoken and written Dutch
- Ability to comprehend and complete questionnaire by phone
- > 18 years

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- No oral food intake
- Coexisting-morbidities affecting taste or smell function
- Uncertainty about the willingness or ability of the patient to comply with the protocol requirements

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	15-07-2019
Aantal proefpersonen:	50
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Ethische beoordeling

Positief advies

Datum:	25-06-2019
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL7827
Ander register	METc UMCG : METc 2019/360

Resultaten